UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
SOUTHWESTERN DIVISION

SARAH D. HOOVER	)	
	)	
	)	
Plaintiff	)	**Case No.: 3:14-cv-5090-BCW**
	)	
v.	)	
	)	
BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	
	)	
	)	
Defendant.	)	
_____	)	

PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

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INTRODUCTION

Plaintiff, Sarah Hoover, a resident of Carthage, Missouri, had Defendant's Mirena intrauterine system ("IUD" or "IUS") placed by a physician. *See* Complaint ("Compl.") ¶ 1, 75. While using Defendant's Mirena, Plaintiff began experiencing severe migraines, dizziness, tinnitus, and vision problems, including blurred vision. *Id*. at ¶ 79. Plaintiff sought treatment and was diagnosed with idiopathic intracranial hypertension (also called pseudotumor cerebri) ("IIH/PTC'). *Id*. at ¶ 80. IIH/PTC is a devastating and potentially permanent brain condition that arises when cerebrospinal fluid ("CSF") in the brain causes increased intracranial pressure in the skull and on a patient's optic nerve, leading to vision problems and in some cases, blindness. *Id*. ¶ 31-32, 38-40. Plaintiff claims use of Defendant's Mirena caused, triggered, and/or contributed to her developing IIH/PTC. *Id*. at ¶ 82-84.

The only drug in Mirena is a synthetic hormone called levonorgestrel ("LNG"), which has been reported to cause, contribute to, trigger, and/or exacerbate the development of IIH/PTC. LNG releasing implants should be immediately removed once a patient is diagnosed with IIH/PTC. *Id*. at ¶ 13, 17, 51-52, 58-61. Other regulated birth controls that release LNG, including Norplant System, specifically warn physicians and patients of the link between LNG and IIH/PTC and its link to risk factors of IIH/PTC, including sudden weight gain. *Id*. ¶ 54-65. Plaintiff claims, in great detail, that Bayer's Mirena, and specifically, the hormone contained in Mirena, LNG, caused her to develop IIH/PTC, a condition that may develop over time because of ongoing exposure to LNG. Further, Bayer failed (and continues to fail) to warn physicians, patients, and the healthcare community of the risks of developing IIH/PTC with use of Mirena, or that Mirena should be removed once a patient is diagnosed with IIH/PTC. Mirena's labeling contains no warning whatsoever of the link between LNG and IIH/PTC. Compl. ¶ 26-27.

Bayer seeks dismissal of Plaintiff's 42-page, 266-paragraph complaint, claiming that it contains "just formulaic recitations of claim elements, devoid of the factual enhancement needed to indicate a plausible basis for liability. *See* Bayer's Motion to Dismiss (DN 4), p. 1-2. Yet throughout Bayer's memorandum, Bayer merely cherry-picks allegations, claiming them to be mere legal conclusions, and ignores the nearly twelve pages full of dozens of paragraphs setting forth facts supporting each of Plaintiff's claims. Bayer filed near-identical motions in several related cases[1] pending in the Western District of Kentucky and the Northern District of Alabama.[2] Notably, Bayer fails to bring this Court's attention to the fact that in both of the Alabama cases—on nearly identical motions alleging the same arguments made here—Honorable William M. Acker, Jr. quickly and easily rejected each of Bayer's arguments. In fact, Judge Acker refused to dismiss any of the claims, except for breach of implied warranty, which he dismissed on state-law grounds not applicable here. *See* Exhibit A, *Houston v. Bayer Healthcare Pharms., Inc.*, 2014 U.S. Dist. LEXIS 43641 (N.D. Ala. March 28, 2014, amended April 3, 2014); *Bridges v. Bayer Healthcare Pharms., Inc.*, Case No.: 2:14-cv-00036-WMA (N.D. Ala. April 3, 2014) (holding that the *Houston* opinion, as amended, applied equally).[3]

As in the related cases, Bayer's motion can be boiled down to only specifically asserting the four following alleged factual deficiencies: 1) the names of the doctors who inserted and removed her Mirena and diagnosed her with IIH/PTC; 2) the State she received her Mirena IUD

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[1] The undersigned counsel represents numerous other women, who have all developed IIH/PTC due to use of Defendant's Mirena, in various cases across the country.

[2] *See Smith v. Bayer Healthcare Pharms., Inc.*, Case No.: 3:14-cv-00006-JGH (W.D. Ky.); *Hardwick v. Bayer Healthcare Pharms., Inc.*, Case No.: 3-14-cv-00082-JGH (W.D. Ky.); *Martin v. Bayer Healthcare Pharms., Inc.*, Case No.: 3:14-cv-00398-TBR; *Babich-Zacharias v. Bayer Healthcare Pharms., Inc.*, 5:14-cv-00101-TBR (W.D. Ky.); *Bridges, et. Al. v. Bayer Healthcare Pharms., Inc.*, Case No.: 2:14-cv-00036-WMA (N.D. Ala.); and *Houston v. Bayer Healthcare Pharms., Inc.*, Case No.: 2:14-cv-00035-WMA (N.D. Ala.).

[3] But see the rulings in *Smith*, *Hardwick*, and *Martin*, in which the Court denied Bayer's motion to dismiss but found that Plaintiffs' complaints needed additional factual detail and granted leave to amend. *Smith*, Case No.: 14-cv-0006 (W.D. Ky. Aug. 13, 2014); *Hardwick*, Case No.: 3:14-cv-00082 (W.D. Ky. Aug. 13, 2014); and *Martin*, Case No.: 3:14-cv-00398 (W.D. Ky. Dec. 9, 2014).

and subsequent medical treatment; 3) the locations of her Mirena IUD placement, removal, and her IIH/PTC diagnosis; and 4) the dates of her Mirena IUD insertion, removal, and her IIH/PTC diagnosis. None of these facts are necessary to state valid claims under any applicable state law. Despite Bayer's claims, federal courts do not require doctor's names, dates, and locations to state adequate claims under Rule 8(a). Bayer fails to identify how any of these alleged deficiencies prevent it from having notice. Moreover, many of these facts will be disclosed in initial disclosures or early in the case. Bayer's motion to dismiss has no merit and should be denied.

Bayer argues that Plaintiff has not sufficiently pled her negligence, design defect, strict liability manufacturing defect, breach of warranty, negligent misrepresentation, and fraud-based claims.[4] But Plaintiff's detailed factual allegations meet the federal pleading standard. The purpose of a Rule 12(b)(6) motion to dismiss is not to test the merits of Plaintiff's case or the alleged insufficiency of the facts. Rather, a properly brought Rule 12(b)(6) motion asks whether if all the factual allegations, taken as true, fail to state claims as a matter of law. Here, Bayer inappropriately seeks to heighten Plaintiff's pleading standard, arguing, in essence, the lack of names, locations and dates warrant dismissal of all claims against it. Yet, Bayer has ample notice of the claims against it and its motion should be denied in its entirety. Alternatively, if this Court deems any of Plaintiff's claims insufficient, Plaintiff respectfully requests leave to amend.

MOTION TO DISMISS STANDARD

Under Rule 8(a), Plaintiff must plead "a short and plain statement of the claim showing the pleader is entitled to relief." To defeat a motion to dismiss for failure to state a claim, Plaintiff must show " 'that the pleader is entitled to relief,' in order to 'give the defendant fair

[4] Although Bayer requests dismissal of the entire complaint, Bayer does not specifically explain how Plaintiff's negligent failure to warn claim, strict liability failure to warn claim, or her punitive damages allegations are insufficient, much less support this implied argument with any authority. Moreover, Plaintiff is not pursuing a manufacturing defect claim. Thus, Bayer's motion to dismiss this non-existent claim should be denied as moot.

notice of what the … claim is and the grounds upon which it rests.'" *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 1964 (2007). This Court "'must accept as true all of the allegations in a complaint' that are applicable to legal conclusions." *Jones Co. Homes, LLC v. Laborers' Int'l Union of North America*, 2010 U.S. Dist. LEXIS 13543, *2 (E.D. Mo. 2010) (quoting *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009)). This standard does not require detailed facts, but rather, enough to state a plausible entitlement to relief. *Twombly*, 550 U.S. at 555. "The purpose of a Rule 12(b)(6) motion to dismiss is to allow a defendant to test whether, as a matter of law, the plaintiff is entitled to legal relief even if everything alleged in the complant is true." *Bihn v. Fifth Third Mortg. Co.*, 2013 U.S. Dist. LEXIS 155701, *6 (S.D. Ohio 2013). Thus, "the motion is not a procedure for resolving a contest between the parties about the facts or the substantive merits of the plaintiff's case.'" *Id*. (quoting 5B Charles Alan Wright and Arthur R. miller, *Federal Practice and Procedure* § 1356 (3d ed. 2004)).

Thus, despite Plaintiff's complaint containing "legal conclusions," the question is whether, taken as a whole, taken as true, and drawing all reasonable inferences therefrom, the facts alleged in Plaintiff's complaint state a claim under Missouri law. Instead of focusing on the facts alleged, Defendant cherry-picks certain legal phrases in Plaintiff's complaint—legal phrases that nevertheless must be made—in an attempt to persuade this Court that those facts have not been pled. The motion should be denied in its entirety.

ARGUMENT

I. PLAINTIFF'S CLAIMS ARE FACTUALLY SUFFICIENT

From the outset, Defendant fails to identify any alleged factual deficiencies that are fatal to any of Plaintiff's claims. Defendant argues that Plaintiff's failure to identify the names of her physicians, the location of her Mirena insertion, removal and medical treatment, and the dates of

her Mirena IUD insertion, removal, and IIH/PTC diagnosis render Plaintiff's entire complaint subject to dismissal. However, Defendant neglects to show how any of these facts are necessary to state her claims, or how the failure to include them deprives it of requisite notice. None of these facts are necessary to sufficiently plead Plaintiff's claims. None of these facts prevent this Court from concluding that Plaintiff's claims plausibly give rise to an entitlement to relief. None of these facts are essential elements of any of Plaintiff's claims.

Plaintiff's complaint lays out, in detail, the basis of her claims against Bayer. Plaintiff claims Bayer manufactured, developed, tested, marketed, distributed, and sold the Mirena IUS that caused her injuries. Compl. ¶ 6. Plaintiff claims the hormone released by Mirena—LNG—causes, contributes to, or otherwise increases the risk of developing IIH/PTC, a condition Plaintiff developed while on Mirena. Compl. ¶ 51-53. Plaintiff claims Defendant's Mirena caused her to develop IIH/PTC. Compl. ¶ 80-84. Plaintiff further claims her IIH/PTC is a result of Mirena's defective nature and Defendant's failure to warn. *See*, e.g., Compl. ¶ 135-159. Plaintiff alleges substantial facts to support these claims, including facts regarding Mirena, its regulatory history, facts about a similar birth control that releases LNG, citations to medical literature describing the association between LNG and IIH/PTC, a description of Defendant's warnings, the inadequacies if those warnings, Bayer's deceptive marketing behavior, adverse events reported with use of Mirena, and detailed descriptions of IIH/PTC and its treatment. These facts are sufficient to support all of Plaintiff's claims against Bayer.

Judge Acker had no trouble rejecting Bayer's "global deficiency" argument:

> As an initial matter, the court disagrees that there exists an abstract sufficiency hurdle, contained in the Federal Rule, that is entirely separate from any substantive law. So long as a plaintiff lists some cause of action in his complaint, the question is whether he has alleged **facts to support that cause of action**, not simply whether he has alleged facts. Indeed, the second prong of the *Iqbal* test, in which the court determines whether the complaint states a plausible claim for

> relief, requires by logical necessity some discussion of the elements of the causes of actions alleged.

Houston, 2014 U.S. Dist. LEXIS 43641 at *4 (emphasis in original).

Upon examination of the complaints in *Houston* and *Bridges* (which are nearly identical to the complaint here), Judge Acker noted that "[e]ven were such a 'global deficiency' principle to exist, the court takes with healthy skepticism defendant's claim that it has no notice here as to why it is being sued." *Id.* At *6. Like the Alabama complaints, Plaintiff spells out her liability theory in the first sentence of her complaint, outlines her injuries and the public evidence linking Mirena's hormone to those injuries, and details numerous causes of action against Bayer. *See Id.* at *6-7, cf. Plaintiff's Compl. at p. 1; Compl. ¶¶ 75-84 (Plaintiff's injuries); Compl. ¶¶ 50-66 (evidence showing a link between LNG and PTC/IIH); Compl. ¶¶ 86-259 (Counts 1-9).

Defendant cites *Bosch v. Bayer Healthcare Pharms. Inc.*, 2013 U.S. Dist. LEXIS 148745 (W.D. Ky. 2013) (*"Bosch I")* to support its argument that Plaintiff must allege dates, locations, and names of physicians in order to sufficiently plead claims against it. *Bosch I*, however, is not informative as the court found "it is neither necessary nor desirable for it to detail the deficiencies in Plaintiffs' complaints." *Id*. at *10. The *Bosch I* court's brief, 3-page order concluded the plaintiffs' claims were factually and legally deficient, but did not specifically address any such deficiency it found fatal under the federal pleading standard. The court did note that the *Bosch I* plaintiffs failed to identify what specific side effects and injuries the three separate plaintiffs suffered. *Id*. at *5-6. Instead, the plaintiffs alleged "certain … health consequences" from use of Mirena, claiming Mirena caused a variety of side effects, but failing to identify any particular injuries. Moreover, the court did not grant Bayer's motion, instead

allowing plaintiffs leave to amend. *Id*. at *10.[5] In the Alabama cases, Judge Acker agreed that *Bosch I* did not support dismissal, finding that it "has no holding that this court can discern, as the court there declined to analyze the complaint before it on the grounds that doing so would provide the plaintiffs an advisory opinion." *Houston*, 2014 U.S. Dist. LEXIS 43461 at *5.[6]

Unlike in the Mirena cases Bayer cites, Plaintiff's claims are factually and legally sufficient. Plaintiff adequately describes her injuries, how they developed, and their relation to Bayer's conduct and product in great detail. Moreover, in light of the *Bosch I* court's decision not to discuss the specific deficiencies rendering the complaint insufficient, Defendant's claim that *Bosch I* supports dismissal is misleading. The court found that the complaint contained factual and legal deficiencies—not that the failure to plead who prescribed and inserted their IUDs and when they were removed and by whom warranted dismissal. *Id*. at *7. Plaintiff's claims involve a latent injury that develops due to LNG exposure over time. Bayer's citation to inapposite cases taken out of context does not support dismissal. Bayer makes no persuasive argument that these alleged deficiencies are "key facts" for notice of the claims against it.

A. Plaintiff's Strict Liability and Negligence Claims are Sufficiently Stated.

Plaintiff sufficiently states her strict liability and negligence claims. Negligence requires 1) a duty of care, 2) breach, 3) causation, and 4) damages. *Kuhn v. Budget Rent-A-Car of Missouri, Inc.*, 876 S.W.2d 668, 672 (Mo. Ct. App. 1994). Strict liability follows the Restatement (Second) of Torts § 402A, which allows for recovery if (1) the defendant sold a product in the

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[5] In *Bosch II*, the court ruled on Bayer's motion to dismiss the *Bosch* plaintiffs' amended complaint. *See Bosch v. Bayer Healthcare Pharms., Inc.*, 2014 U.S. Dist. LEXIS 48055 (W.D. Ky. April 7, 2014) (*"Bosch II"*). Although several claims were dismissed under Kentucky law, the court did not dismiss a single claim for failure to plead facts Bayer alleges are necessary here. Thus, neither *Bosch I* nor *Bosch II* supports dismissal here.

[6] Bayer's citation to *Gonzalez v. Bayer Healthcare Pharms., Inc.*, 930 F.Supp.2d 808 (S.D. Tex. 2013) is also misplaced. *Gonzalez* dealt primarily with insufficient allegations to defeat a rebuttable presumption under a Texas statute that drug manufacturers cannot be liable for failure to warn if a drug's label is FDA-approved. Missouri has no such statute.

course of its business; (2) the product was then in a defective condition, unreasonably dangerous when put to a reasonably anticipated use; (3) the product was used in a manner reasonably anticipated; and (4) the plaintiff was damaged as a direct result of such defective condition as existed when the product was sold. *Lay v. P&G Health Care*, 37 S.W.3d 310, 325 (Mo. Ct. App. 2000). Missouri's products liability statute also states that liability may lie if the "product was then unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics, and the plaintiff was damaged as a direct result of the product being sold without an adequate warning." Mo. Rev. Stat. § 537.760(b). Three separate theories of liability are set forth in Missouri's product liability statute, including design defect, manufacturing defect, and failure to warn. *Peters v. GMC*, 200 S.W.3d 1, 17 (Mo. Ct. App. 2006). All of these theories, except for a manufacturing defect theory, which is not being pursued, are amply supported in Plaintiff's complaint under either a strict liability or negligence standard.

Plaintiff claims Mirena is defectively designed, and in a defective condition unreasonably dangerous for the uses for which it is intended and for which it was used by the Plaintiff, and that Defendant failed to warn—in any manner—of the risks of developing IIH/PTC. *See* Compl. ¶ 103, 119-120, 127, 146, 150, 156-157, 166-182. Plaintiff claims Bayer owed Plaintiff a variety of duties, including a duty to design Mirena to prevent foreseeable harm, to adequately test Mirena, to adequately and continuously warn of its risks, and a duty not to place a product unreasonably dangerous to consumers on the market. *See*, e.g., Compl. ¶ 102, 135, 150. Bayer breached these duties because it knew or should have known that LNG caused and/or contributed to the development of IIH/PTC, and because Bayer failed to design, test, market, label, and warn of the risks of Mirena as a reasonable manufacturer with this knowledge would. *Id.* Plaintiff claims an ordinarily prudent manufacturer, with this knowledge and in the exercise of due care,

would not have placed Mirena on the market. Compl. ¶ 81-84. Defendant placed (and continues to place) an unreasonably dangerous product on the market, without adequate warnings, and asks for dismissal under an inappropriate pleading standard that is not supported by law.

Bayer claims that Plaintiff's design defect claim is insufficiently pled because the Complaint fails to identify "what specific design aspects of Mirena were allegedly defective," and instead "parrots the elements of a design-defect claim, utilizing buzz words and phrases." *See* Bayer's Memo (DN 5), p. 7. However, Plaintiff sufficiently pleads the "design aspect" of Mirena is defective. *See, e.g.*, Compl. ¶ 51-52 (alleging LNG causes and contributes to the development of IIH/PTC, which Plaintiff developed while using Defendant's Mirena). Defendant cannot plausibly tell this Court that Plaintiff has not pled that she is basing her defect allegations on the hormone contained in Mirena and the levels of that hormone, which causes and contributes to the development of IIH/PTC. Plaintiff has pled her Mirena was defective because it exposes users, long-term, to LNG, which renders the product unreasonably dangerous. Plaintiff has also pled that the failure by Defendant to warn of the risks associated with exposure to LNG, and in particular, the risks of developing papilledema and/or IIH/PTC rendered Defendant's Mirena defective and unreasonably dangerous. Missouri law requires nothing further. *See also, In re NuvaRing Prods. Liab. Litig. v. Organon USA, Inc.*, 2013 U.S. Dist. LEXIS 99735, *98-100 (E.D. Mo. 2013) (allegations that a design defect existed based on use of third-generation progestins, along with admissible causation evidence, sufficient to defeat summary judgment on plaintiffs' design defect claim). *Turner v. Mylan*, 2010 U.S. Dist. LEXIS, 38819, *6-7 (E.D. Mo. 2010) (allegations in a wrongful death case "that the defendants designed, manufactured and marketed the specific product; that the decedent used the product properly for its intended use on a date certain; and that the product directly and proximately caused her

death," sufficiently stated under *Twombly*); *Naiser v. Unilever United States, Inc.*, 2013 U.S. Dist. LEXIS 140515 (W.D. Ky. Sept. 30, 2013) (allegations that ingredient in defendants' hair smoothing product was unreasonably dangerous and caused plaintiffs' injuries sufficient to show how the product was defective).

Plaintiff has sufficiently pled that exposure to the hormone in Defendant's Mirena IUD caused her IIH/PTC, and that Bayer is liable under both strict liability and negligence. Compl. ¶ 52, 79-83. Defendant asserts that Plaintiff has not alleged how it breached any duties with respect to Mirena's design and how its breach proximately caused her injuries. Yet Plaintiff claims Bayer breached its duty to 1) design and market a product reasonably safe for its intended uses; 2) adequately conduct pre-market testing, including testing for the safety of exposure to LNG and the development of IIH/PTC; and 3) warn of the risks associated with LNG, including IIH/PTC, both initially upon marketing Mirena and during its post-marketing period, despite numerous adverse events alerting Defendant to its risks. *See*, e.g., Compl. ¶ 102. Plaintiff alleges throughout her complaint that LNG—the only drug product in Mirena—is unreasonably dangerous and proximately caused her injuries. Compl. ¶ 17, 52-53, 67. Defendant had ample knowledge that Mirena's directly contributes to the development of IIH/PTC and did nothing to test, design, or warn of the foreseeable risks in an appropriate manner to prevent them. Compl. ¶ 66. And Plaintiff claims other forms of birth control that do not contain LNG do not pose these unreasonable risks. Compl. ¶ 101, 103. These allegations, supported with dozens of paragraphs of facts, are sufficient. The motion to dismiss must be denied.

B. Plaintiff Sufficiently Pleads Fraud Under Rule 9(b).

Federal Rule of Civil Procedure 9(b) requires Plaintiff to plead with particularity the circumstances constituting fraud or mistake. The Eighth Circuit interprets Rule 9(b) to require

details including essentially the "who, what, where, when and how" of the alleged fraud. *Lemery v. Duroso*, 2009 U.S. Dist. LEXIS 36492, *7 (E.D. Mo. 2009). However, Rule 9(b) must be interpreted "in harmony with the principles of notice pleading." *Abels v. Farmers Commodities Corp.*, 259 F.3d 910, 920 (8th Cir. 2001). Thus, Rule 9(b)'s particularity requirement is intended to provide defendants with a more specific form of notice—not to require a plaintiff to specify every potential fact relevant to her fraud claim.

Here, Plaintiff's factual allegations satisfy Rule 9(b). Plaintiff claims that Bayer, initially upon marketing Mirena and continuing to the present, fraudulently concealed the risks of Mirena and misrepresented its safety with respect to the risks of developing IIH/PTC. *See*, e.g., Compl. ¶ 184-185, 189, 194, 211. Plaintiff claims these fraudulent misrepresentations occurred and continue to occur in Mirena's labeling, patient package insert, and through Bayer's direct to consumer marketing, including advertisements and its Simple Style Statements Program. *See*, e.g., Compl. ¶ 22-27, 66-73, 98, 110, 138-141, 148, 155, 194, 203-211. Plaintiff claims Bayer fraudulently misrepresents that Mirena is safe for long-term use as contraception and to treat heavy menstrual bleeding, despite Bayer's knowledge to the contrary because LNG causes, contributes to, and/or exacerbates the IIH/PTC condition. *Id*. Plaintiff claims Bayer fraudulently concealed the risks of developing IIH/PTC with use of its product in an effort to defraud consumers and the healthcare community. Compl. ¶ 184-186. Plaintiff identifies specific misrepresentations contained in Bayer's Mirena labeling. *See*, e.g., Compl. ¶ 22-27, 184-186. Likewise, Plaintiff claims Defendant made these false representations to the FDA, to patients, to prescribing physicians, the healthcare community, and the public. *See*, e.g., Compl. ¶ 98, 185.

These allegations are sufficient. In a recent Eastern District of Missouri case, the court held that allegations that two talc manufacturers conspired to form a "Talc Interested Party Task

Force" with the intent to prevent consumers from learning the harmful effects of talc met Rule 9(b)'s particularity requirement. *Blaes v. Johnson & Johnson*, 2014 U.S. Dist. LEXIS 167974, *6-7 (E.D. Mo. Dec. 4, 2014). Specifically, the plaintiff alleged the two defendants "pooled resources" to "collectively defend talc use" through "biased research" the defendants funded and held out as "scientific reports." Similarly, in a case involving product liability claims and the prescription drug Reglan, the plaintiffs claimed that the "Defendants' Reglan/MCP drug information was false and misleading and caused her to ingest MCP for longer than 12 weeks, which ultimately caused her to develop tardive dyskinesia." *Neeley v. Wolters Kluwer Health, Inc.*, 2013 U.S. Dist. LEXIS 106191, *57 (E.D. Mo. 2013). Ultimately, these allegations were enough to plead fraud and misrepresentation under Rule 9(b). *Id.*

Likewise, in *Bosch II*, the court refused to dismiss the plaintiff's fraud-based claims, holding that allegations that the plaintiffs received communications from Bayer around the time of their Mirena insertions, which misrepresented the safety of Mirena and failed to warn them of specific risks, satisfied Rule 9(b). *Bosch II*, 2014 U.S. Dist. LEXIS 48055 at *37-39. Ultimately:

> With these allegations, Plaintiffs have identified the type and source of communications—i.e. pamphlets, brochures, and commercials from or by Bayer. They have also identified when they received such communications—i.e., "on or around" the time of their Mirena® insertions. Further, by alleging that the communications represented that Mirena® had been tested and was found to be safe, despite the fact that it produced dangerous side effects, including interstitial cystitis and birth defects, Plaintiffs have alleged the content of the communications. Finally, Plaintiffs have alleged that the communications "omitted, concealed, downplayed, underreported, and underestimated the dangers of MIRENA®"—and that they, and their physicians relied on the communications. … The Court finds that these allegations are sufficient. The allegations place Bayer on notice of the alleged fraud such that Bayer can address Plaintiff's fraud claims in a meaningful way.

Id. at *38-39 (internal complaint cites omitted). Plaintiff makes all the same claims and more.

Bayer's motion to dismiss Plaintiff's fraud claims should be denied. Plaintiff adequately states the "who, what, where, when, and how" requirements of Rule 9(b). Alternatively, Plaintiff should be granted leave to amend should this Court deem her fraud claims insufficiently pled.

C. Plaintiff States Valid Breach of Warranty Claims.

Plaintiff's breach of warranty claims also sufficiently meet federal pleading standards. Defendant fails to meet its burden under Rule 12(b)(6) to show Plaintiff has failed to state her breach of warranty claims, instead just reciting the claims' elements and stating Plaintiff has sufficiently not pled them in conclusory terms. That is not enough. Plaintiff claims Defendant made express and implied warranties both directly to the Plaintiff through its patient information booklet and to her physicians through its physician labeling. *See*, e.g., Compl. ¶ 66-67, 102, 192-193, 203. And Plaintiff claims she and her physicians relied upon Defendant's warranties. *See* Compl. ¶ 77 (alleging Plaintiff and her physicians relied upon the representations in the package insert, patient information booklet, or otherwise disseminated by Defendant); *see also*, Compl. ¶ 203, 204-205, 219-223. Moreover, Plaintiff claims Defendant's Mirena is not merchantable or safe or fit for its intended use because it causes or contributes to the development of IIH/PTC, a foreseeable risk Defendants were aware of. *See* Compl. ¶ 196. These statements are sufficient to plead warranty claims under Missouri law. Moreover, in *Pfitzer v. Smith & Wesson Corp.*, 2014 U.S. Dist. LEXIS 196886 (E.D. Mo. 2014), a case relied upon by Defendant, the court determined the proper remedy for insufficient breach of warranty allegations was to grant leave to amend. Thus, should this court determine Plaintiff's breach of warranty claims are not properly pled, Plaintiff should be afforded the opportunity to amend her complaint.

Further, in *Bosch II*, the Court denied Bayer's motion to dismiss on the same argument as made here. *See Bosch II*, 2014 LEXIS 48055 at *45-47. *Bosch II* found that Plaintiffs

sufficiently pled that Bayer made express warranties, which may support a viable express warranty action. *See Bosch II*, 2014 LEXIS 48055, at *47. Plaintiffs claimed Bayer "expressly warranted that Mirena was safe and well accepted by users" and "expressly represented to Plaintiffs, their physicians, healthcare providers, and/or the FDA that Mirena was safe and fit for use for the purposes intended." *Id.* at 46. Plaintiff here alleges Bayer expressly warranted Mirena to be safe for Plaintiff and members of the public. Further, "Defendant expressly represented to Plaintiff, her physician(s), healthcare providers, and/or the FDA that Mirena was safe and fit for the uses in which it is intended." *See* Compl. ¶ 203, 207. This is sufficient to state breach of warranty claims under Missouri law. In any event, Defendant fails to meet its burden to show these claims should be dismissed and there motion must be denied.

D. Plaintiff Adequately States a Negligent Misrepresentation Claim Under Missouri Law.

Finally, Defendant's argument that Plaintiff has not sufficiently alleged a negligent misrepresentation claim should be rejected. Yet again, Defendant cherry-picks allegations Plaintiff makes and ignores dozens of paragraphs spanning multiple pages, which allege specific facts of the misrepresentations made by Defendant that Plaintiff and her doctors relied upon. Defendant fails to meet its burden that Plaintiff's negligent misrepresentation claim, or any of Plaintiff's claims for that matter, must be dismissed at this stage of the proceedings.

Plaintiff has adequately stated that Bayer has made affirmative false statements with respect to Mirena, consistent with Missouri law. *See* Compl. ¶ 217-223. Plaintiff alleges that Defendant affirmatively misrepresented the safety of Mirena for use as a contraceptive and that it would not lead to papilledema and/or IIH/PTC. But in any event, "[c]laims for both fraudulent and negligent misrepresentation can arise from the failure to disclose information." *Kesselring v. St. Louis Group*, 74 S.W.3d 809, 814 (Mo. Ct. App. 2002). For misrepresentations based upon a

failure to disclose, there must be a duty disclose. *Id*. "A duty to speak arises where a party has superior knowledge or information that is not reasonably available to the other." *Hess v. Chase Manhattan Bank, USA, N.A.*, 220 S.W.3d 758, 765 (Mo. 2007). Plaintiff's allegations clearly meet this standard. Moreover, Plaintiff claims Defendant had a duty to not misrepresent the safety and provide all relevant safety information to users imposed upon it by federal law. *See* Compl. ¶ 222-224. Thus, Plaintiff has sufficiently alleged under Missouri law that Defendant made both affirmative misrepresentations and those based on its failure to disclose. Because Plaintiff states a valid negligent misrepresentation claim, Bayer's motion to dismiss this claim should be denied.

II. ALTERNATIVELY, PLAINTIFF SHOULD BE GRANTED LEAVE TO AMEND

Alternatively, should this Court find any of Plaintiff's claims insufficient, Plaintiff respectfully requests leave to amend her complaint. Courts "should freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). Rule 15 "'plainly embodies a liberal amendment policy.'" *Bosch*, 2013 U.S. Dist. LEXIS at *8 (granting plaintiff in a Mirena case leave to amend her complaint) (quoting *Morse v. McWhorter*, 290 F.3d 795, 800 (6th Cir. 2002)). Thus, should this Court deem any of Plaintiff's claims insufficiently pled, Plaintiff respectfully requests leave to amend in accordance with Fed. R. Civ. P. 15.

CONCLUSION

Ultimately, Defendant cherry-picks allegations from Plaintiff's complaint and ignores dozens of fact paragraphs that support each of her claims. Defendant fails to meet its burden that any of her claims should be dismissed. For all the foregoing reasons, Defendant's Motion to Dismiss must be denied. Alternatively, to the extent this court finds any of Plaintiff's claims deficient, this Court should allow Plaintiff leave to amend her claim pursuant to Rule 15.

Respectfully submitted,

GORI, JULIAN & ASSOC.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing was filed via the ECF/CM system with the Clerk of the Court, which will have sent notice to all attorneys of record in this matter on this, the 29th day of December, 2014.

/s/ *D. Todd Mathews*
D. Todd Mathews